

510(k) Summary

DEC 16 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: May. 30, 2011

1. Company and Correspondent making the submission:

Name – CyberMed, Inc.

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Contact – Mr. Yong Ki Im / RA Manager

2. Device :

Trade/proprietary name : OnDemand3D^{G2}

Common Name : Picture archiving and communications system

Classification Name : System, image processing, radiological

3. Predicate Devices :

Manufacturer: : CyberMed, Inc.

Device: : OnDemand3DTM

510(k) Number: : K070464 (Decision Date – 03/16/2007)

Manufacturer: : Materialise, N.V.

Device: : SimPlant System

510(k) Number: : K033849 (Decision Date – 05/25/2004)

Manufacturer: : Anatomage, Inc.

Device: : Invivo Dental

510(k) Number: : K070803 (Decision Date – 04/06/2007)

Manufacturer: : GE Medical systems SCS

Device: : CardIQ Fusion
510(k) Number: : K061370 (Decision Date – 05/30/2006)

4. Classifications Names & Citations :

21CFR 892.2050, LLZ, Picture archiving and communications system, Class2

5. Description :

1) General Description

OnDemand3D^{G2} is a personal computer based dental imaging software which loads DICOM images taken from CT, MR and provides 3D visualization and 2D analysis, various MPR (Multi-Planar Reconstruction) functions for further rapid and precise diagnosis. It is also intended to plan an implant surgery, fabricate a surgical guide according to the plan, superimpose and stitch multi DICOM data sets, mark anatomical landmark from CT data and provide analyzed data for orthodontic treatment while software provides 2D image viewing module enabling 2D image acquisition specialized in 2D scanned image supporting DICOM, BITMAP, JPG, TIF.

OnDemand3D^{G2} is designed to provide with users and familiar user-interface easy. Also OnDemand3D^{G2} makes it possible to manage medical images more easily and provides advanced tools for 2D and 3D analysis with various rendering functions. The main functions of OnDemand3D^{G2} are as follows.

2) Main Function

(1) DBM(Data base Manager)

The operator can use DICOM images stored in Master database, Local databases or Remote PACS servers more conveniently with user-familiar interface such as Window explorer. DBM supports CD-R/RW to keep necessary DICOM images in CD directly. DBM supports to make multiple Local databases so it is very convenient for multiple users on one system.

(2) LightBox

LightBox supports to load different types of DICOM images such as 8/12/16 bits gray images and color images. LightBox provides 'CINE Player' to display multi-frame DICOM images. LightBox supports a preview image on Window print and

DICOM print screen.

(3) Dental Reformat

Dental Reformat makes it possible to reconstruct Panoramic and Cross sectional images. Conventional imaging solutions are supported, and also new imaging solutions such as Volume Rendering, 3D Scout are supported. The layout and images are optimized for Reporting.

(4) 3D

3D makes it possible to switch rendering mode such as VR(Volume Rendering), MIP/MinIP more easily and conveniently. 3D provides more accurate images by using various rendering functions such as MPR Rotating, Curve, 3D Zoom, Clip.

(5) X-ray Generation

X-ray Generation makes it possible to create X-ray images for cephalometric analysis. Lateral X-ray image and frontal X-ray image can be generated in X-ray Generation module.

(6) Report

Report makes it possible to make a report more easily by using intuitive user interface and also export it to HTML format document. The operator can capture necessary images on all screens of OnDemand3D^{G2} with Pane-Capture/Region-Capture function and insert the captured images to Report very easily.

(7) In2guide

In2Guide is designed for the purpose of easy implant planning and short operating time with high accuracy. In2Guide provides functionality for diagnosis, implant planning and implant, abutment library of many manufacturers.

(8) Fusion

Fusion is a visualization tool using a registration technique to combine and show the image data from different modalities such as CT,MRI and PET in one window at the same time. A Fusion window consists of each MPR image of the Primary, Secondary and Fused pane matched between two images. In the case of images

comes from same patients we can compare the changes between pre and post-operation. Fusion provides functions for loading two series of Primary and Secondary images and saving the fused image as a new DICOM series.

(9) 3D Ceph

3D Ceph provides precise analysis result using formulas based on anatomical landmarks of patient. Landmarks and formulas can be customizable.

The key features of 3D Ceph are comparing pre-operation with post-operation by superimposition, photo mapping and 2D X-ray image generation.

(10) X-Image

X-Image module is management solution for both 2D and 3D images. X-Image sorts images by patient name and it handles images from Panorama, Cephalometric, Intraoral, Conebeam CT. The operator can also view 2D images with built in filter and image tools.

3) Information of the image format

OnDemand3D^{G2} can load only DCM files and save results as DCM, BMP and JPG files.

- DCM : DICOM (Digital Image Communication in Medicine) is a Standard Protocol to exchange and transfer the data acquired by Medical Image devices such as a CT, MR, 3D US, etc. It is designated as a Standard Protocol by ACR-NEMA (American College of Radiology-National Electrical Manufacturers Association) and now adopted by most Medical Imaging Devices. OnDemand3D^{G2} 2.0 is adaptable technically for all data of DICOM 3.0.

Reference : Digital Imaging and Communications in Medicine (DICOM) ACR-NEMA Standards Publication PS 3.1~PS 3.16 2003.

- BMP : The standard bit-mapped graphics format used in the Windows environment. By convention, graphics files in the BMP format end with a BMP extension. BMP files store graphics in a format called device-independent bitmap (DIB).
- JPG/JPEG : Short for "Joint Photographic Experts Group", the original name of the committee that wrote the standard. JPG is one of the image file formats supported

on the Web. JPG images support 16 million colors and are best suited for photographs and complex graphics.

4) Compression

- Compression Method : Lossless Compression

6. Indication for use :

The OnDemand3DG2 is intended for use as a software package which loads DICOM images from CT, MR, X-Ray, stores those and provides 3D visualization and 2D analysis, various MPR (Multi-Planar Reconstruction) functions for further rapid and precise diagnosis.

It also provides the following functions as shown below.

- 1) Functions for implant surgery planning and fabricating a surgical guide according to the plan
- 2) Functions to combine and show the image data from different modalities such as CT, MRI and PET in one window at the same time
- 3) Functions to create orthodontic analysis using 3D volume data
- 4) Functions to sort and save DICOM files, Project Files and 2D image files from different modality [Panorama, Cephalometric, intraoral] under a single patient name

7. Comparison with predicate device :

CyberMed, Inc., ensures that the OnDemand3D^{G2}, Picture archiving and communications system is substantially equivalent to OnDemand3DTM of CyberMed, Inc., SimPlant System of Materialise N.V., Invivo Dental of Anatomage Inc., CardIQ Fusion of GE Medical systems SCS.

The similarities are as follows.

User, Computer Platform, Communication, PACS Server, DICOM data transferring, Archiving data Format, Image format In, Image Compression, Image Archive, Image Display, Image Reformation, 3D Image Construction, Image Projection, Image Edit, Basic Image Operation, Measurements, Other Function, Report, Printing

And the additional similarities are as follows.

- 1) Similarity between OnDemand3D^{G2} In2Guide module and SimPlant System

- 2) Similarity between OnDemand3D^{G2} Fusion module and CardIQ Fusion
- 3) Similarity between OnDemand3D^{G2} 3D Ceph module and Invivo Dental

And the Differences are as follows.

- 1) Differences between OnDemand3D^{G2} In2Guide module and SimPlant System
- 2) Differences between OnDemand3D^{G2} 3D Ceph module and Invivo Dental (3D Analysis)

There are a little bit of differences between the OnDemand3D^{G2} and Predicate Devices (OnDemand3DTM, SimPlant System, Invivo Dental, CardIQ Fusion) as above. But eventually, these differences do not cause any problems in the safety and effectiveness.

8. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification CyberMed, Inc. concludes that OnDemand3D^{G2} is safe and effective and substantially equivalent to predicate devices as described herein.

- 9. CyberMed, Inc. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

CyberMed Inc.
% Mr. Marc M. Mouser
Engineering Leader & FDA Office Coordinator,
Program Reviewer
Underwriters Laboratories Inc.
2600 NW Lake Road
CAMAS WA 98607

DEC 16 2011

Re: K113543

Trade/Device Name: Picture Archiving Communications System/OnDemand3D^{G2}
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 1, 2011
Received: December 1, 2011

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, reading "Mary S. Pastel". The signature is fluid and cursive, with the first name "Mary" being more prominent than the last name "Pastel".

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number(if known): K113543

Device Name: Picture Archiving Communications System / OnDemand3D^{G2}

Indications for Use:

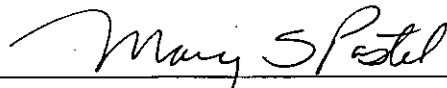
The OnDemand3D^{G2} is intended for use as a software package which loads DICOM images from CT, MR, X-Ray, stores those and provides 3D visualization and 2D analysis, various MPR (Multi-Planar Reconstruction) functions for further rapid and precise diagnosis.

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Prescription Use ☒ AND/OR Over-The-Counter Use ☐
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)



Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)